340B Program Compliance: Hospital Self-Assessment Checklist

General 340B Program Infrastructure

1. **Does the entity have current written policies and procedures for all areas of 340B compliance, including all child site locations?**

2. **Do the policies and procedures address the following areas:**

   a. Entity's 340B program eligibility requirements (patient, prescriber, location)?
   b. Auditable records demonstrating compliance with all 340B requirements?
   c. Internal controls in place to demonstrate ongoing compliance with all 340B requirements?
   d. Inclusion of 340B compliance in the annual internal audit/compliance plan?
   e. Contract Pharmacy Service Agreements compliance with the twelve (12) contract pharmacy essential compliance elements as defined by the Health Resources and Services Administration (HRSA)?
   f. Specific 340B program compliance duties, training, and development of responsible staff?
   g. 340B enrollment, recertification, and change request process?
   h. 340B procurement, inventory management, and dispensing?
   i. 340B compliance monitoring and reporting processes?

3. **At a minimum, have employees in the following areas been educated regarding 340B compliance: pharmacy, billing, information technology, finance, reimbursement, nursing, compliance, and medical records?**

4. **Has the entity's 340B compliance been audited internally (*i.e.*, corporate compliance or internal audit)? Does the scope of any audit(s) include Contract Pharmacy arrangements?**

5. **For any internal audits conducted, were action plans developed for any issues identified, and were the action plans implemented in a timely manner?**

6. **For significant findings identified, was HRSA notified and informed of the entity's corrective action plan?**

7. **Is the entity prepared to annually attest to the following essential 340B program compliance requirements?**

   a. Office of Pharmacy Affairs (OPA) Database entry is complete, accurate, and correct?
   b. Entity meets 340B eligibility requirements?
   c. Entity maintains auditable records?
   d. Systems/controls are in place to ensure compliance?
   e. All contract pharmacy arrangements are in compliance and entity has obtained sufficient information to confirm compliance?
   f. Entity has contacted the OPA for any breach identified?
   g. Entity acknowledges possibility of payment to manufacturers for failure to notify the OPA in a timely fashion?

8. **Has the entity practiced obtaining data to support 340B compliance in the event of an HRSA or manufacturer audit?**

   a. Cost reports and any amendments?
   b. Provider NPI listing and contractual arrangements?
   c. Dispensing records at the specific patient/drug level?
   d. Purchasing records (GPO, WAC, and 340B)?
   e. Flow charts of all 340B processes including a listing of all information systems?
   f. List of providers eligible to write 340B prescriptions (includes employed and contracted physicians)?
   g. Ability to identify any providers that could have had the ability to write 340B prescriptions during the audit time frame (*i.e.*, medical staff, rotating physicians, physicians who are part of a group contract such as emergency department coverage)?
   h. List of contract pharmacies utilized and current contracts?

Duplicate Discounts

1. **Has the entity informed OPA immediately of any changes to the OPA website/Medicaid exclusion file?**

2. **Do the entity's Medicaid billing practices align with its information listed on the OPA website/Medicaid Exclusion File? Is this periodically reviewed for accuracy?**

3. **Has the entity reviewed its state-specific Medicaid program requirements to ensure compliance?**

4. **Is the entity aware of current initiatives at the state level regarding whether covered entities can retain their 340B savings or whether they must bill at acquisition cost?**

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Covered Entity Eligibility

1. **Has the entity's data on the OPA database been reviewed to ensure it is complete, accurate, and correct?**
2. **Does the entity only use 340B drugs in outpatient clinics that are registered on the OPA database (or within the four walls of the parent) and reimbursable on the most recently filed cost report?**

Patient Eligibility (Diversion)

1. **Does the entity have a relationship with the patient and maintain records of the patient's healthcare? Does the relationship extend beyond the prescribing of 340B drugs?**
2. **Does the entity maintain an eligible prescriber listing? Is this listing routinely compared against a listing of professionals with contractual or other arrangements with the entity?**
3. **Are auditable records maintained to ensure the patient is an outpatient at time of the prescription?**

Contract Pharmacy Arrangements

1. **At a minimum, do all contract pharmacy arrangements include the following elements:**

   a. Written agreement between the entity and the contract pharmacy?
   b. List of all contract pharmacy locations?
   c. Use of "ship to, bill to" arrangements?
   d. Controls for preventing duplicate discounts and diversion (*i.e.*, tracking systems)?
   e. Exclusion of Medicaid beneficiaries unless a separate arrangement has been entered into with the state Medicaid agency?
   f. Documentation and audit requirements to demonstrate compliance?

2. **Has the entity obtained sufficient information from the contract pharmacy provider to ensure compliance with applicable 340B requirements?**
3. **Are controls in place to ensure the contract pharmacy verifies patient and prescriber for eligibility?**
4. **Have any independent audits of the contract pharmacy arrangements been performed as recommended by HRSA?**

340B Program Intent and Community Benefit

1. **Does the entity have a communication strategy regarding how it uses the savings from the 340B program to benefit low-income and uninsured patients?**
2. **Has the entity assessed its charity care policies in relation to its use of 340B savings?**

Procurement and Inventory

1. **Does the inventory system prohibit the entity from obtaining covered outpatient drugs from a group purchasing organization (GPO)— *i.e.*, disproportionate share hospitals, children's hospitals, free-standing cancer clinics?**
2. **Does the entity maintain records of 340B-related transactions for a period of time (per written policies) in a readily retrievable and auditable format?**
3. **For physical inventories, are all 340B drugs separated from non-340B drugs (*i.e.*, GPO)?**
4. **Does the entity have controls established to ensure orphan drugs are not purchased under the 340B program?**
5. **If the entity uses a split-billing software for mixed-use areas, are procedures clearly written and processes outlined (flowchart) to address the following elements:**

   a. Process used for determining inpatient vs. outpatient status?
   b. Basis for replenishment orders?
   c. Tracking of 340B, inpatient and non-340B drugs (*i.e.*, GPO)?
   d. Accurate data capture (*i.e.*, time stamps, EMR split-billing system interfaces, patient eligibility)?